INDEX

	Page
Opinions below	1
Jurisdiction	1
Questions presented	2
Statement	2
Argument	4
Conclusion	7

CITATIONS

Cases:

American School of Magnetic Healing v. *McAnnulty*, 187 U.S. 94 6

Irwin v. *Federal Trade Commission*, 143 F. 2d 316 6

Kordel v. *United States*, 335 U.S. 345 5

United States v. *Article * * * "110 V Vapozone,"* 194 F. Supp. 332 6

United States v. *Kaadt*, 171 F. 2d 600 6

United States v. *353 Cases * * * Mountain Valley Mineral Water*, 247 F. 2d 473 6

United States v. *Urbuteit*, 335 U.S. 355 5

United States v. *Urbuteit*, 336 U.S. 804 5

V. E. Irons, Inc. v. *United States*, 244 F. 2d 34, certiorari denied, 354 U.S. 923 6

Statute:

21 U.S.C. 352(a) 2

711-579—63

In the Supreme Court of the United States

OCTOBER TERM, 1963

No. 536

MARVIN SCHERR, D/B/A JENASOL CO., PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 30–47) is reported at 320 F. 2d 564. Two opinions by the district court (Pet. App. 11–29) are reported at 200 F. Supp. 1 and 201 F. Supp. 915.

JURISDICTION

The judgment of the court of appeals was entered on July 16, 1963. The petition for a writ of certiorari was filed on October 10, 1963. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether promotional literature intended for use in distribution and sale of a drug is labeling under 21 U.S.C. 321(m), when the literature and drug are being held for such future use by a salesman.

2. Whether findings of fact as to the therapeutic merit of a drug which are based on the testimony of highly qualified medical and scientific expert witnesses must be set aside because of recognition by such witnesses that difference of opinion existed as to the drug's qualities.

STATEMENT

Pursuant to a libel of information filed in the United States District Court for the Western District of Washington, seizure was made of 23 bottles of a drug labeled in part "Jenasol RJ Formula '60' Capsules" (hereinafter referred to as "Jenasol"). The drug is a product containing a key substance called "royal jelly", which is the special food fed by worker bees to a newly-hatched bee destined to become a queen, and various vitamins. The libel (R. 9a) charged that the drug was misbranded under 21 U.S.C. 352(a) because its labeling (R. 151b–160b) made a number of therapeutic claims (chiefly that the drug had highly beneficial qualities for rejuvenating the aging and sexually inadequate, but including promises of greater well-being for almost anyone) that were false and misleading.

A claim to the seized drug was made by Marvin Schere, d/b/a Jenasol Company, and the case was re-

moved to the District of New Jersey for trial. After a trial to the court, without a jury, the drug was adjudged misbranded and the 23 bottles ordered condemned; 200 F. Supp. 1 (Pet. App. 11). Upon application of the claimant, additional findings were made and, upon motion of the United States, a decree of injunction forbidding further shipments of the misbranded drug was entered; 201 F. Supp. 915 (Pet. App. 24). Upon appeal, the order of condemnation was affirmed, but the order of injunction reversed. The issues raised by petitioner relate only to the condemnation decree.

1. The facts pertinent to the question whether the literature constituted labeling were stipulated (Exhibit G-1, R. 572a). The 23 bottles were shipped by the petitioner from New York to O. E. Haugland, an agent of the petitioner in Milton, Washington, on July 7, 1958. Three of the four items of labeling were sent by petitioner to Mr. Haugland on May 15, 1958; the fourth was printed by Mr. Haugland from mats supplied by the petitioner. Mr. Haugland assembled the literature into "sets." He would deliver a "set" of literature with each bottle of "Jenasol" sold to a customer. He also distributed literature to past and potential customers of "Jenasol" to solicit purchases. All the items of literature seized were to be used in this manner. The 23 bottles of "Jenasol" were ordered by him in his capacity as agent as stock for future sales. He was holding the seized "Jenasol" and literature for that purpose in his bedroom closet.

2. In order to establish that "Jenasol" would not perform as claimed the United States presented the testimony of several medical and scientific experts (R. 2b–94b) who were recognized by both courts below as highly qualified. See 200 F. Supp. 1, 2–4 (Pet. App. 13–17), and 320 F. 2d 564, 570 (Pet. App. 41). Their testimony, some of it based on animal and human experiments, is summarized in the first opinion of the district court (Pet. App. 13–17). It was to the effect that "Jenasol" had none of the effects claimed in the labeling, except in a limited vitamin deficiency condition. Specifically, royal jelly in their opinion had no effect on sexual vitality (R. 20b–34b, 56b–58b, 69b) and would not be effective in treating underdeveloped children (R. 41b). Two experts stated that their opinions represented the consensus of medical opinion (R. 34b, 91b). Upon extensive cross-examination (R. 41a–493a), based largely on writings not in evidence indicating that "royal jelly" may have some therapeutic merit, the government's experts acknowledged that differing opinions regarding "royal jelly" existed. The petitioner, in his direct case, offered the testimony of two practicing physicians, whose opinions in large part contradicted the government's evidence (R. 494a–536a).

ARGUMENT

1. Petitioner, although he does not deny that the literature was intended for use with the product, argues that it was not labeling "accompanying" the product because there was no showing that the litera-

ture seized, had been associated with the product in connection with an actual use. Petitioner relies on the fact that in *Kordel* v. *United States*, 335 U.S. 345 and *United States* v. *Urbuteit*, 335 U.S. 355, 336 U.S. 804, while ruling that literature not physically attached to the container may be labeling, this Court made reference to the actual use of the literature shown in those cases. However, as the court below noted, there is nothing in either case indicating that proof of use (in the sense of a display of the particular seized drug and literature to a potential customer) is necessarily required. It is enough that the literature and drug be associated together as part of a plan to sell the drug. In *Urbuteit, supra,* and *Kordel, supra,* the literature was held to be labeling when the devices and drugs were shipped in commerce; the actual use of the literature with the devices and drugs after such shipment had no bearing on *when* the literature became labeling.

Petitioner's question as to "Exactly when, during this life cycle of the 23 bottles, can it be stated that the legal 'accompaniment' occurred" can be readily answered (Pet. 7). It occurred when the bottles were shipped in interstate commerce as part of the distribution plan established by stipulation. The drugs were then misbranded and remained so while in commerce and while held for sale by Mr. Haugland. What was said in *United States* v. *Urbuteit, supra,* 335 U.S. at 357–358, in refusing to attribute significance to the fact that the devices and literature were shipped at different times is applicable here: "The Act is not concerned with the purification of the

stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics." The result reached here is in accord with the only other appellate decision on the point. *United States* v. *353 Cases* * * * *Mountain Valley Mineral Water*, 247 F. 2d 473, 478 (C.A. 8). See, also, *United States* v. *Article* * * * *"110 V Vapozone*, 194 F. Supp. 332 (N.D. Cal.), which upheld a libel charging that a device was accompanied by leaflets intended for use to promote the sale thereof.

2. On the basis of the testimony of highly qualified experts, the district court found that "royal jelly", the key ingredient of "Jenasol," did not have the therapeutic rejuvenating claims attributed to it by the accompanying literature. When unqualified claims are made as to the therapeutic value of a drug and there is conflict of opinion as to whether these claims can be justified, it is the duty of the trier of fact to resolve the conflict; the existence of a conflict does not prevent a finding of misbranding. *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34, 43 (C.A. 1), certiorari denied, 354 U.S. 923, *United States* v. *Kaadt*, 171 F. 2d 600, 603 (C.A. 7). Cf. *Irwin* v. *Federal Trade Commission*, 143 F. 2d 316, 323 (C.A. 8) and cases cited therein.[1] The fact that government wit-

[1] *American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94, relied upon by petitioner, involved a finding of *fraud* by the Postmaster General. The rule of that case, that a mail service could not be stopped because of the making of claims as to which medical opinion differed, has no applicability under the Federal Food, Drug, and Cosmetic Act of 1938, which contains no fraud requirement.

nesses on cross-examination showed awareness of other opinions does not weaken the force of their testimony based on their own analyses and studies.

CONCLUSION

The judgment of the court below was correct. No significant issue of law is presented to this Court. It is respectfully submitted that the petition for a writ of certiorari should be denied.

ARCHIBALD COX,
Solicitor General.
HERBERT J. MILLER, JR.,
Assistant Attorney General.
BEATRICE ROSENBERG,
DUANE L. NELSON,
Attorneys.

NOVEMBER 1963.

U. S. GOVERNMENT PRINTING OFFICE 1963